

**EPA REGISTRATION NUMBER 87122-1**

# Material Sent for Data Extraction

Reg # 87122-1

Description: Registration

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 8/31/11

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 6/1/11

☐ Other: \_\_\_\_\_

☒ Decision #: 440456

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Mindy Ondish

Phone: 703-605-0723 Division: RD/PM Team 25

Date: 8/31/11



**U.S. ENVIRONMENTAL PROTECTION AGENCY**  
**Office of Pesticide Programs**  
**Registration Division (7505P)**  
**Ariel Rios Building**  
**1200 Pennsylvania Ave., NW**  
**Washington, D.C. 20460**

**NOTICE OF PESTICIDE:**

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

EPA Registration  
Number:

87122-1

Date of Issuance:

AUG 31 2011

Term of Issuance: **Unconditional**

Name of Pesticide Product:

**NAB Nico Tech**

Name and Address of Registrant (include ZIP Code):

**Zibo NAB Agrochemicals, Ltd.**  
**North of National High-Tech Industrial Development Zone**  
**Shandong Province, Zibo City, 256410, China**

**c/o Pyxis Regulatory Consulting, Inc.**  
**4110 136<sup>th</sup> Street, NW**  
**Gig Harbor, WA 98332**

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA provided that you:

1. Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data.
2. Submit one-year Storage Stability (Guideline 830.6317) and Corrosion Characteristics (Guideline 830.6320) studies within eighteen (18) months from the date of this notice.

The Basic Confidential Statement of Formula (CSF) dated June 1, 2011 is acceptable.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the revised final printed label before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA §6(e). Your release for shipment of the product constitutes acceptance of these conditions.

If you have any questions regarding this Notice, please contact Mindy Ondish at (703) 605-0723 or at [ondish.mindy@epa.gov](mailto:ondish.mindy@epa.gov).

Signature of Approving Official:

**Kable Bo Davis**  
**Product Manager 25**  
**Herbicide Branch**  
**Registration Division (7505P)**

Date:

AUG 31 2011

**NAB Nico Tech**  
FOR USE IN FORMULATING HERBICIDES ONLY

ACTIVE INGREDIENT:

Nicosulfuron (2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethyl-3-pyridinecarboxamide).....98.0%

OTHER INGREDIENTS.....2.0%

TOTAL.....100.0%

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

<b>FIRST AID</b>	
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 -20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call a Poison Control Center or doctor for treatment advice.</li> </ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 -20 minutes.</li> <li>• Call a Poison Control Center or doctor for treatment advice.</li> </ul>
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>NOTE TO PHYSICIAN</b>	
No specific antidote. Treat symptomatically.	
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. <b>FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE CALL THE NATIONAL POISON CONTROL CENTER AT 1-800-900-4044</b>	

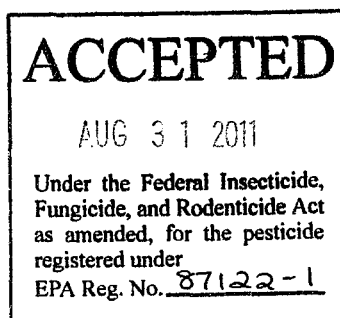
EPA Reg. No. 87122-1

EPA Est. No.

Manufactured for:  
Zibo NAB Agrochemicals Ltd.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

BATCH NO.:

NET CONTENTS:



**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION**

Causes moderate eye irritation. Harmful if absorbed through skin or swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirement of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

Only for formulation into herbicide products for the following uses: (1) corn, including field corn (high lysine, waxy, white or other food grade corn hybrids), field corn grown for seed, popcorn, and sweet corn; (2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) uses for experimental purposes that are in compliance with USEPA requirements.

Each formulator is responsible for obtaining EPA registration for his own end use products.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container tightly closed and in a cool, dry place away from food, drink and feed. If spilled, do not flush to waterways. In case of spill, contain material and dispose of as waste.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL: Liner:** Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. When completely empty offer for recycling if available or dispose of liner in a sanitary landfill." **Outer Drum:** Nonrefillable container. Do not reuse or refill this container. When completely empty offer for recycling if available or dispose of drum in a sanitary landfill.

**IMPORTANT INFORMATION  
READ BEFORE USING PRODUCT**

**CONDITIONS OF SALE AND  
LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Zibo NAB Agrochemicals Ltd. warrants that this

product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Zibo NAB Agrochemicals Ltd., and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ZIBO NAB AGROCHEMICALS LTD. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOT ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law, Zibo NAB Agrochemicals Ltd. or Seller shall not be liable for any industrial, incidental, consequential, or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER AND BUYER, AND THE EXCLUSIVE LIABILITY OF ZIBO NAB AGROCHEMICALS LTD. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT SHALL BE, AT THE ELECTION OF ZIBO NAB AGROCHEMICALS LTD. OR SELLER, THE REPLACEMENT OF THE PRODUCT, OR, COMPENSATION LIMITED TO DAMAGES NOT EXCEEDING THE FAIR MARKET PURCHASE PRICE, AND SHALL NOT INCLUDE INCIDENTAL OR CONSEQUENTIAL DAMAGES.**

Zibo NAB Agrochemicals Ltd. and Seller offer this product, and Buyer and user accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by the duly authorized representative of Zibo NAB Agrochemicals Ltd.

## REGISTRATION NOTE FOR RECORD

*This document may contain CBI. For internal Agency use only.*

<b>EPA Reg. No./ File Symbol:</b>	87122-R (1)
<b>Product Name:</b>	NAB Nico Tech
<b>Application Date:</b>	9/27/10
<b>Action Description:</b>	R330

### **PRODUCT CHEMISTRY:** (DP384654; 6/17/11)

Revised basic CSF dated 6/1/11 acceptable

Submitted product chemistry studies (MRID 48245701-06)

### **Data Gap: Storage Stability & Corrosion Characteristics**

### **ACUTE TOXICITY:** (DP384655; 6/16/11 & DP392622; 8/30/11)

Submitted acute tox 6pack studies (MRID 48245707-12)

Dermal sensitization study was unacceptable due to poor positive control

Registrant chose to selectively cite dermal sensitization studies (MRID 41360117 & 41082604), which was acceptable.

**Tox Category III for Acute Oral, Acute Dermal, and Primary Eye Irritation**

**Tox Category IV for Acute Inhalation and Primary Dermal Irritation**

**Not a Dermal Sensitizer**

### **GENERIC DATA:**

Selective cite-all on nicosulfuron generic data support

### **LABEL REVIEW:**

Me-too of Reg# 81598-6

### **COMMENTS:**

98% Nicosulfuron Technical

Sent 75-day deficiency letter on 7/6/11 for label and dermal sensitization issues;  
received revised label and data matrix to selectively cite dermal studies on 8/3/11

### **DECISION:**

Unconditional Registration with Data Requirements

<b>Reviewer:</b>	Mindy Ondish	<b>Date:</b>	8/30/11
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 30, 2011

**MEMORANDUM**

Subject: Name of Pesticide Product: NAB NICO TECH  
EPA Reg. No. /File Symbol: 87122-R  
DP Barcode: DP 392622  
Decision No.: 440456  
Action Code: R330  
PC Codes: 129008 (Nicosulfuron: 98%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*August 30 - 2011*  
*B. Backus*

To: Mindy Ondish/Kable Davis RM 25  
Herbicide Branch  
Registration Division (7505P)

Registrant: ZIBO NAB AGROCHEMICALS, LTD.

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129008 Nicosulfuron	
2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino] sulfonyl]-N,N-dimethyl-3-pyridinecarboxamide	98.0%
<u>Other Ingredient(s):</u>	2.0%
TOTAL	100.0%

**ACTION REQUESTED:** The Risk Manager requests:

"The previous acute tox review DP384655 dated 6/16/11 concluded that the submitted dermal sensitization study (MRID 48245712) was unacceptable due to poor positive controls. The registrant was given options on how to satisfy the data requirement, with one of the choices being that they could use the cite-all method of support. Instead, the registrant has chosen to use [the] selective cite-all (MRID 41360117 & 41082604) as method of support.



“Therefore, please review the cited dermal sensitization studies and determine if they satisfy the data requirement for the proposed product. I believe the cited studies relate to 352-535 (but am not certain), and have included a copy of the basic CSF for reference. A copy of the proposed CSF which was accepted by CHEM and the label are also included. Please review ASAP since this is a resubmission.”

## **BACKGROUND:**

The material received for review includes CSFs for 352-535 and 87122-R, the proposed label for 87122-R, and a copy of the previous (dated June 16, 2011 under DP 384655) TRB review for 87122-R.

## **COMMENTS AND RECOMMENDATIONS:**

1. According to OPPIN Query, the study in MRID 41082604 has the following citation: *Brock, W. (1987) Closed-patch Repeated Insult Dermal Sensitization Study (Buehler Method) with INV-9360-7 in Guinea Pigs: Du Pont HLR 429-87. Unpublished study prepared by Du Pont Haskell Laboratory. 28 p.* This study was submitted to support the following actions and EPA Reg. Nos.: 9F3763, 352-535 and 352-534. EPA Reg. No. 352-535 is Du Pont Nicosulfuron Technical (with a label declaration of 93.0% active ingredient). No records were found for EPA Reg. No. 352-534.
2. According to OPPIN Query, the study in MRID 41360117 has the following citation: *Brock, W. (1989) Closed-patch Repeated Insult Dermal Sensitization Study (Buehler Method) with INV-9360-7 in Guinea Pigs: Revised: Addendum to Report HLR 429-87; Med. Res. No. 4581-469. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 7 p.* According to OPPIN, the study was submitted to support 352-1, but no records were found for this registration number. It is concluded that the material in MRID 41360117 is additional material regarding the study in MRID 41082604.
3. After comparing the CSFs for 87122-R and EPA Reg. No. 352-535, TRB concludes that the two products are toxicologically similar.
4. From the Nicosulfuron HED Chapter of the Reregistration Eligibility Decision Document (RED) dated November 30, 2004, the dermal sensitization study (MRID 41082604) is classified as acceptable/guideline. Nicosulfuron is a not a sensitizer.
5. On the basis of the information indicated above, TRB concludes that the citation of MRIDs 41082604 and 41360117 adequately satisfies the dermal sensitization study requirement to support the registration of 87122-R, which is not a dermal sensitizer.
6. Based on the previous (June 16, 2011, DP Barcode 384655) TRB toxicity review for 87122-R, and with the resolution of the dermal sensitization study requirement, the following would be the precautionary and first aid labeling for 87122-R (NAB NICO TECH), as obtained from the TRB Label Review System:

**PRODUCT ID #:** 087122-00001

**PRODUCT NAME:** NAB NICO TECH

#### **PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

#### **Hazards to Humans and Domestic Animals:**

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]\*

\*[Protective eyewear may be specified, if appropriate].

#### **First Aid:**

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

7. The registrant has proposed a toxicity category III inhalation first aid statement. This is acceptable.
8. For the purposes of this action, TRB has not rereviewed the cited material in MRIDs 41082604 and 41360117.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Zibo NAB Agrochemicals Ltd 4110 136th St. NW Gig Harbor, WA 98332, 253- 853-7369	EPA Registration Number/File Symbol 87122-R
Active Ingredient(s) and/or representative test compound(s) Nicosulfuron	Date 7/27/2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food, Terrestrial non-food	Product Name NAB Nico Tech

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M. Tillman</i>	Date 7/27/2011	Typed or Printed Name and Title Ann M. Tillman, Agent
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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## DATA MATRIX

Date July 27, 2011			EPA Reg. No./File Symbol 87122-R		Page 1 of 12
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550	Product Identity and Composition	48245701	Zibo NAB Agrochemicals Ltd.	OWN	
830.1600	Description of Materials Used to Produce the Product	48245701	Zibo NAB Agrochemicals Ltd.	OWN	
830.1620	Description of Production Process	48245701	Zibo NAB Agrochemicals Ltd.	OWN	
830.1650	Description of Formulation Process				Not Required <sup>1</sup>
830.1670	Discussion of Formation of Impurities	48245701	Zibo NAB Agrochemicals Ltd.	OWN	
830.1700	Preliminary Analysis	48245702	Zibo NAB Agrochemicals Ltd.	OWN	
830.1750	Certified Limits	48245701	Zibo NAB Agrochemicals Ltd.	OWN	
830.1800	Enforcement Analytical Method	48245703	Zibo NAB Agrochemicals Ltd.	OWN	
830.6302	Color	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.6303	Physical State	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.6304	Odor	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	48245704	Zibo NAB Agrochemicals Ltd.	OWN	Data
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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401 M Street, S.W.

WASHINGTON, D.C. 20460

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## DATA MATRIX


Date July 27, 2011			EPA Reg. No./File Symbol 87122-R	Page 2 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction: Chemical Incompatibility	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Data Waiver <sup>2</sup>
830.6315	Flammability	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Waiver <sup>3</sup>
830.6316	Explosibility	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Waiver <sup>4</sup>
830.6317	Storage Stability	48245706	Zibo NAB Agrochemicals Ltd.	OWN	PR-92-5 <sup>5</sup>
830.6319	Miscibility	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Not Applicable <sup>6</sup>
830.6320	Corrosion Characteristics	48245706	Zibo NAB Agrochemicals Ltd.	OWN	PR-92-5 <sup>5</sup>
830.6321	Dielectric Breakdown Voltage	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Not Required <sup>6</sup>
830.7000	pH	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.7050	UV/Visible Absorption	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.7100	Viscosity	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Not Applicable <sup>6</sup>
830.7200	Melting Point/Melting Range	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.7220	Boiling Point/Boiling Range	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Not Required <sup>7</sup>
830.7300	Density/Relative Density/Pulk Density	48245704	Zibo NAB Agrochemicals Ltd.	OWN	
830.7370	Dissociation Constants in Water	48245704	Zibo NAB Agrochemicals Ltd.	PL	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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401 M Street, S.W.  
WASHINGTON, D.C. 20460

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Date July 27, 2011			EPA Reg. No./File Symbol 87122-R	Page 3 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle Size, Fiber Length, and Diameter Distribution	48245706	Zibo NAB Agrochemicals Ltd.	OWN	Not Applicable <sup>6</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	48245704	Zibo NAB Agrochemicals Ltd.	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	48245705	Zibo NAB Agrochemicals Ltd.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	48245704	Zibo NAB Agrochemicals Ltd.	PL	
<b>Generic Data Requirements</b>					
850.2100 (71-1)	Acute Avian Oral Toxicity	Cite-All		PAY	
850.2200 (71-2)	Avian Dietary Toxicity	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011


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## DATA MATRIX

Date July 27, 2011			EPA Reg. No./File Symbol 87122-R		Page 4 of 12
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2300 (71-4)	Avian Reproduction	Cite-All		PAY	
850.2400 (71-3)	Wild Mammal Toxicity				Not required <sup>8</sup>
850.1075 (72-1)	Freshwater Fish Toxicity	40924216 40924217 41360109 41360110		OLD OLD OLD OLD	See endnote <sup>9</sup>
850.1010 (72-2)	Freshwater Invertebrate Toxicity	Cite-All		PAY	
850.1075 (72-3(a))	Estuarine/Marine Toxicity: Fish	Cite-All		PAY	
850.1025, 850.1035, 850.1045, 850.1055 (72-3(b,c))	Estuarine/Marine Toxicity: Mollusk and Shrimp	Cite-All		PAY	
850.1300 (72-4)	Aquatic Invertebrate Life Cycle	Cite-All		PAY	
850.1500 (72-5)	Fish Life Cycle	Cite-All		PAY	
850.1710, 850.1730, 850.1850 (165-4)	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.3020 (141-1)	Honeybee Acute Contact Toxicity	Cite-All		PAY	
850.4100 (122-1(a))	Tier 1: Seed Germination/Seedling Emergence	Cite-All		PAY	
850.4150 (122-1(b))	Tier 1: Vegetative Vigor	Cite-All		PAY	
850.4400 (122-2)	Tier 1: Aquatic Plant Growth	Cite-All		PAY	
850.4100 (123-1(a))	Tier 1: Seed Germination/Seedling Emergence	Cite-All		PAY	
850.4150 (123-1(b))	Tier 2: Vegetative Vigor	Cite-All		PAY	
850.4400 (123-2)	Tier 2: Aquatic Plant Growth	Cite-All		PAY	
870.1100	Acute Oral Toxicity: Rat	Volume 7	Zibo NAB Agrochemicals Ltd.	OWN	
870.1200	Acute Dermal Toxicity: Rat	Volume 8	Zibo NAB Agrochemicals Ltd.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	Volume 9	Zibo NAB Agrochemicals Ltd.	OWN	
870.2400	Primary Eye Irritation: Rabbit	Volume 10	Zibo NAB Agrochemicals Ltd.	OWN	
870.2500	Primary Dermal Irritation	Volume 11	Zibo NAB Agrochemicals Ltd.	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011




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## DATA MATRIX

Date July 27, 2011			EPA Reg. No./File Symbol 87122-R	Page 6 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Dermal Sensitization	41360117 41082604	E. I. DuPont de Nemours & Co. E. I. DuPont de Nemours & Co.	OLD OLD	
870.6100 (81-8)	Acute Neurotoxicity – Rat	Cite-All		PAY	
870.3100 (82-1)	90-Day Oral - Rodent	Cite-All		PAY	
870.3150 (82-1)	90-Day Oral – Non-rodent	Cite-All		PAY	
870.3200 (82-2)	21/28-Day Dermal	Cite-All		PAY	
870.4100 (83-1)	Chronic Feeding: Rat	Cite-All		PAY	
83-1(b)	Chronic Feeding: Non-Rodent				Not required
870.4200 (83-2)	Carcinogenicity	Cite-All		PAY	
870.3700 (83-3)	Prenatal Developmental Toxicity – Rat and Rabbit	Cite-All		PAY	
870.3800 (83-4)	Reproduction and Fertility Effects	Cite-All		PAY	
870.5100 (84-2(a))	Bacterial Reverse Mutation Assay	Cite-All		PAY	
870.5300, 870.5375 (84-2(b))	<i>In vitro</i> Mammalian Cell Assay	Cite-All		PAY	
870.5385, 870.5395 (84-4)	<i>In vivo</i> Cytogenetics	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011


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## DATA MATRIX


Date July 27, 2011			EPA Reg. No./File Symbol 87122-R		Page 7 of 12
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200 (82-5(a))	90-Day Neurotoxicity – Rat	Cite-All		PAY	
870.7485 (85-1)	Metabolism and Pharmacokinetics	Cite-All		PAY	
870.7800	Immunotoxicity	Cite-All		PAY	
875.1100	Dermal Outdoor Exposure	Cite-All		PAY	
875.1200	Dermal Indoor Exposure				Not required <sup>10</sup>
875.1300	Inhalation Outdoor Exposure	Cite-All		PAY	
875.1400	Inhalation Indoor Exposure				Not required <sup>11</sup>
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues	Cite-All		PAY	
875.2200	Soil Residue Dissipation	Cite-All		PAY	
875.2300	Indoor Surface Residue Dissipation				Not required <sup>12</sup>
875.2400	Dermal Exposure	Cite-All		PAY	
875.2500	Inhalation Exposure	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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## DATA MATRIX


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Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120 (161-1)	Hydrolysis	40924220		OLD	See endnote <sup>13</sup>
835.2240 (161-2)	Photodegradation in Water	Cite-All		PAY	
835.2410 (161-3)	Photodegradation on Soil	Cite-All		PAY	
835.4100 (162-1)	Aerobic Soil Metabolism	Cite-All		PAY	
835.4200 (162-2)	Anaerobic Soil Metabolism	Cite-All		PAY	
835.4400 (162-3)	Anaerobic Aquatic Metabolism	Cite-All		PAY	
835.4300 (162-4)	Aerobic Aquatic Metabolism	Cite-All		PAY	
835.1230, 835.1240 (163-1)	Leaching and Adsorption/Desorption	Cite-All		PAY	
835.6100 (164-1)	Terrestrial Field Dissipation Study	Cite-All		PAY	
835.6200 (164-2)	Aquatic (Sediment) Field Dissipation Study				Not required
835.6300 (164-3)	Forestry Field Dissipation Study				Not required
See 850.1710, 860.1400, 860.1850 for 165-4, 165-3 and 165-1 citations, respectively.					
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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## DATA MATRIX


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Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1100 (171-2)	Chemical Identity	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
860.1200 (171-3)	Directions for Use	See label			
860.1300 (171-4(a))	Nature of the Residue in Plants	41082626		OLD	See endnote <sup>14</sup>
860.1300 (171-4(b))	Nature of the Residue in Livestock	Cite-All		PAY	
860.1340 (171-4(c),(d))	Residue Analytical Methods	41082632 41472101 43023102		OLD OLD OLD	See endnote <sup>15</sup>
860.1380 (171-4(e))	Storage Stability	41082626 43344401		OLD OLD	See endnote <sup>16</sup>
860.1480 (171-4(j))	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs				Not required <sup>17</sup>
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Corn	41082629 43344402		OLD OLD	See endnote <sup>18</sup>
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520 (171-4(I))	Magnitude of Residue in Processed Food/Feed – Corn	41082630 43344403		OLD OLD	See endnote <sup>19</sup>
860.1850 (165-1)	Confined Crop Rotation Study	Cite-All		PAY	
860.1900	Field Accumulation in Rotational Crops	Cite-All		PAY	
201-1	Droplet Size Spectrum	Cite-All		PAY	
202-1	Droplet Size Spectrum	Cite-All		PAY	
Zibo NAB Agrochemicals Ltd. will make offers-to-pay to the following companies on the data submitters list of March 31, 2010.					
		Cite-All	E. I. DuPont de Nemours and Co. Inc.	PAY	
		Cite-All	Cheminova A/S	PAY	
		Cite-All	BASF Corporation	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

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## DATA MATRIX

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Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Agan Chem. Mfg. Ltd.	PAY	
		Cite-All	Albaugh Inc.	PAY	
		Cite-All	Makhteshim-Agan of North America Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Cheminova Inc.	PAY	
		Cite-All	ISK Biosciences Corp.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	FIFRA Endangered Species Task Force, LLC	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Gro-Pro LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011


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Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Rotam Ltd.	PAY	
		Cite-All	Etigra LLC	PAY	
		Cite-All	Rotam Agrochemical Co. Ltd.	PAY	
		Cite-All	Sharda USA LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jul. 27, 2011

## Endnotes for Data Matrix for NAB Nico Tech

- 
- <sup>1</sup> **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- <sup>2</sup> **830.6314** - Zibo NAB Agrochemicals Ltd. requests a waiver from the requirement for determination of the chemical incompatibility (oxidation/reduction). Nicosulfuron does not contain any material that would be considered to be an oxidizing or reducing agent (please refer to the Confidential Statement of Formula for NAB Nico Tech). The MSDS for this product indicates that the following materials can be used as appropriate fire extinguishing agents: foam, dry chemical, carbon dioxide, or water spray. Under DOT regulations, nicosulfuron is not considered hazardous when shipped. HMIS and NFPA ratings indicate this material is not highly reactive (rating of 0) nor flammable (rating of 1). Sufficient emergency response information is available for handling nicosulfuron technical. Therefore, Zibo NAB Agrochemicals Ltd. respectfully requests a waiver from the requirement of these data for NAB Nico Tech.
- <sup>3</sup> **830.6315** - Zibo NAB Agrochemicals Ltd. requests a waiver from the requirement of this data requirement since NAB Nico Tech is a solid and is not expected to be flammable. Please refer to the Confidential Statement of Formula for NAB Nico Tech.
- <sup>4</sup> **830.6316** - Zibo NAB Agrochemicals Ltd. requests a waiver from this data requirement because nicosulfuron does not have the chemical bonds or functional groups associated with explosive chemicals. Please refer to the Confidential Statement of Formula for NAB Nico Tech.
- <sup>5</sup> **830.6317, 830.6320** - Per PR Notice 92-5, these data are not required to be submitted unless specifically requested by the Agency. Zibo NAB Agrochemicals Ltd. agrees to conduct these studies if required and requests that the study be made a condition of registration.
- <sup>6</sup> **830.6319, 830.6321, 830.7100, 830.7520** - NAB Nico Tech is a solid and not an emulsifiable concentrate and is not to be diluted with petroleum solvents. Therefore, miscibility data are not applicable to this technical. NAB Nico Tech is not to be used around electrical equipment and data for dielectric breakdown constant are not required for technical materials. NAB Nico Tech is a solid and not a liquid, therefore, viscosity data are not applicable to this product. Zibo NAB Agrochemicals Ltd. is seeking a waiver for this data requirement for NAB Nico Tech because the product is not a fibrous material nor a water-insoluble material.
- <sup>7</sup> **830.7220** - NAB Nico Tech is a solid and boiling point data are not required for solids. Data for melting point are required for solids. See Guideline 830.7200.
- <sup>8</sup> **850.2400 (71-3)** - These data are not required for the registration of nicosulfuron (please refer to the 870 series). No data have been submitted to support this registration.
- <sup>9</sup> **850.1017 (72-1)** - According to March 2, 1990 EPA memo, the studies cited are considered acceptable and satisfy the data requirement.
- <sup>10</sup> **875.1200** - Product not proposed for application indoors.
- <sup>11</sup> **875.1400** - Product not proposed for application indoors.
- <sup>12</sup> **875.2300** - Product not proposed for application indoors.
- <sup>13</sup> **835.2120 (161-1)** - According to a Feb. 22, 1990 EPA memo, the study cited is considered acceptable and satisfies the data requirement.
- <sup>14</sup> **860.1300 (171-4(a))** - According to an April 23, 1990 EPA memo and HED TRED risk assessment, the study cited is considered acceptable and satisfies the data requirement.
- <sup>15</sup> **860.1340 (171-4(c,d))** - According to an April 23, 1990 EPA memo, the studies cited, plus responsive submissions, satisfy the data requirement.
- <sup>16</sup> **860.1380 (171-4(e))** - According to an April 23, 1990 EPA memo, the study cited and subsequent additional submissions appear to be acceptable and satisfies the data requirement.



## Endnotes for Data Matrix for NAB Nico Tech

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- <sup>17</sup> **860.1480 (171-4(j))** – According to an April 23, 1990 EPA memo and HED TRED risk assessments, these data are not required because residue data did not demonstrate detectable residues.
- <sup>18</sup> **860.1500 (171-4(k))** – According to an April 23, 1990 EPA memo and HED TRED risk assessments, the studies cited appear to be acceptable and satisfy the data requirement.
- <sup>19</sup> **860.1520 (171-4(l))** – According to an April 23, 1990 EPA memo and HED TRED risk assessments, the studies cited appear to be acceptable and satisfy the data requirement.



淄博新农基农药化工有限公司  
ZIBO NAB AGROCHEMICALS CO.,LTD.

OCT 21 2009

21.10.2009

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U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. (contact information below) is authorized to represent Zibo NAB Agrochemicals Ltd. (EPA Co. No. pending) before the US Environmental Protection Agency and California Department of Pesticide Regulation in all matters regarding our pesticide registrations and applications for registrations for nicosulfuron pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332  
T: (253) 853-7369  
F: (253) 853-5516

If you have any questions, please do not hesitate to contact me.

Sincerely,

*Changlu Shao*

(Frank Shao)  
President  
Zibo NAB Agrochemicals Ltd.

cc: Pyxis Regulatory Consulting, Inc.

地址: 山东省淄博市开发区北首博丰南路  
电话: 0086-533-8409995 8407222

邮编: 256410  
传真: 0086-533-8409985

# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
087122-R	July 27, 2011	087122-R.20110727.NAB Nico Tech label.v2.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature  
Ann M. Tillman  
Consultant, Zibo NAB Agrochemicals Ltd.

July 27, 2011  
Date

**PYXIS REGULATORY CONSULTING, INC.**

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
[www.PyxisRC.com](http://www.PyxisRC.com)

July 27, 2011

**OVERNIGHT DELIVERY**

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U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Zibo NAB Agrochemicals, Ltd.  
NAB Nico Tech (EPA File Symbol 87122-R)  
Response to Deficiencies per EPA Letter Dated July 6, 2011

Dear Mr. Davis/Ms. Ondish,

On behalf of Zibo NAB Agrochemicals, Ltd., we are submitting a response to the deficiencies identified in your letter dated July 6, 2011 for NAB Nico Tech (EPA File Symbol 87122-R):

Zibo NAB Agrochemicals Ltd. will use selective cite method of support to satisfy OPPTS 870.2600. The data matrix has been revised.

The label was revised per the comments in the July 6, 2011 letter.

In support of this response, we submit the following documents:

1. Application for Pesticide Registration (EPA Form 8570-1)
2. Three (3) copies of the revised label for NAB Nico Tech
3. One (1) copy of the revised label with changes tracked
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Letter of Authorization

We trust you will find this response complete. However, please feel free to contact me ((253) 853-7369, [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 87122-R	2. EPA Product Manager B. Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zibo NAB Agrochemicals Ltd./NAB Nico Tech	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Zibo NAB Agrochemicals Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>July 6, 2011</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.


Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised administrative documents including revised label in response to EPA letter dated July 6, 2011.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Pyxis Regulatory Consulting, Inc.	Title Agent	Telephone No. (include Area Code) (253)-853-7369
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature  FOR:	3. Title Consultant	
4. Typed Name Ann M. Tillman	5. Date 7/27/2011	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Via Email

July 6, 2011

OPP Decision Number: D-440456

Ann M. Tillman, Agent  
Zibo NAB Agrochemicals, Ltd.  
c/o Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> Street, NW  
Gig Harbor, WA 98332  
Ann@PyxisRC.com

Subject: Application Deficiency  
Product Name: NAB Nico Tech  
EPA File Symbol: 87122-R  
Application Date: September 27, 2010  
EPA Receipt Date: September 29, 2010

Dear Ms. Tillman:

The application referred to above has been determined, pursuant to 40 CFR §152.105, that it is incomplete or that further information is needed to complete the Agency's review. Therefore, the application is considered deficient. The items specified below must be addressed before processing of the application can be completed. If such deficiencies cannot be corrected within 75 days from the date of this letter, you must notify the Agency within those 75 days of the date on which you expect to complete the application. If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by you. Any subsequent submission relating to the application must be submitted as a new application. As you see fit, you may also withdraw the registration application.

**PRIA Due Date: October 20, 2011    75-days from today: September 19, 2011**

The deficiencies identified in the Agency's review at this time are:

1. The dermal sensitization study (MRID 48245712) has been classified as unacceptable based on inadequate positive control. The positive control study was not conducted within 6 months as required by OPPTS 870.2600. You must either a) submit a positive control assay conducted within the 6-month time period of the study on the product, b) cite another dermal sensitization study conducted on this product, c) use the cite-all method of support to satisfy this data requirement, or d) amend labeling to classify this product as a dermal sensitizer. A copy of the acute toxicity review dated June 16, 2011 is enclosed for reference.
2. The proposed labeling for this product submitted on June 1, 2011 is unacceptable. The following changes must be made:
  - a. Under FIRST AID, move the IF SWALLOWED statement so that it is directly below the IF ON SKIN OR CLOTHING statement. The IF INHALED statement is optional for this product and may be removed.
  - b. Change the EPA Reg. No. to "87122-1".
  - c. Add an U.S. address as a point of contact on the label.
  - d. Change the heading in bold to read "**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**".
  - e. Change the above section's statement in bold so it reads "Causes **moderate** eye irritation. Harmful if absorbed through skin **or swallowed**. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, **using tobacco, or using the toilet**. Remove and wash contaminated clothing before reuse."
  - f. If option 1d is chosen, also add "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals." to the above.
  - g. At the bottom of page 2, change the sentence in bold so it reads "The Directions for Use of this product **must** be followed carefully."
  - h. On page 3, add "TO THE EXTENT CONSISTENT WITH APPLICABLE LAW," directly in front of "THE EXCLUSIVE REMEDY OF THE USER..."

Page 3 of 3  
Application Deficiency  
EPA File Symbol: 87122-R

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

Please contact Mindy Ondish by phone at 703-605-0723 or by e-mail at [ondish.mindy@epa.gov](mailto:ondish.mindy@epa.gov) with a response and for any questions concerning this letter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', with a long horizontal flourish extending to the right.

Kable Bo Davis  
Product Manager 25  
Herbicide Branch  
Registration Division (7505P)

Enclosure: Acute toxicity review dated June 16, 2011 (DP384655)



## DATA EVALUATION RECORD

### NICOSULFURON (Nicosulfuron Technical)

**STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OPPTS 870.1100; OECD 423]  
ACUTE DERMAL TOXICITY - RAT [OPPTS 870.1200; OECD 402]  
ACUTE INHALATION TOXICITY - RAT [OPPTS 870.1300; OECD 403]  
ACUTE EYE IRRITATION - RABBIT [OPPTS 870.2400; OECD 405]  
ACUTE DERMAL IRRITATION - RABBIT [OPPTS 870.2500; OECD 404]  
DERMAL SENSITIZATION - GUINEA PIG [OPPTS 870.2600; OECD 406]**


**MRID 48245707, 48245708, 48245709, 48245710, 48245711, and 48245712**

Prepared for  
Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Prepared by  
Summitec Corporation  
9724 Kingston Pike, Suite 602  
Knoxville, TN 37922

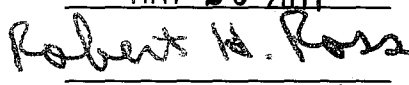
Task Order No. 3-B-07

Primary Reviewer:  
Susan Chang, M.S.

Signature: 


Date: MAY 25 2011

Secondary Reviewers:  
Robert Ross, M.S.

Signature: 

Date: MAY 25 2011

Kowetha Mack, Ph.D., D.A.B.T., Program Manager

Signature: 

Date: MAY 25 2011

Quality Assurance:  
Angie Edmonds, B.S.

Signature: 

Date: MAY 25 2011

#### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 16, 2011

**MEMORANDUM**

Subject: Name of Pesticide Product: NAB NICO TECH  
EPA Reg. No. /File Symbol: 87122-R  
DP Barcode: DP 384655  
Decision No.: 440456  
Action Code: R330  
PC Codes: 129008 (Nicosulfuron: 98%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

*Byron T. Backus*  
*June 16 2011*  
*W. Hasler*  
*Team Leader, Toxicology*  
*TRB*

To: Kable Davis RM 25  
Herbicide Branch  
Registration Division (7505P)

Registrant: ZIBO NAB AGROCHEMICALS, LTD.

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129008 Nicosulfuron	
2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino] sulfonyl]-N,N-dimethyl-3-pyridinecarboxamide	98.0%
<u>Other Ingredient(s):</u>	<u>2.0%</u>
TOTAL	100.0%

**ACTION REQUESTED:** The Risk Manager requests:

“Please review the attached studies and determine if they meet the Guideline[s]. Provide the precautionary language for the label based on your review and determine if this product is substantially similar to 81598-6 from an acute toxicity point of view.”

## BACKGROUND:

The material received for review includes a set of 6 acute toxicity studies (MRID 48245707: acute oral LD50; 48245708: acute dermal LD50; 48245709: acute inhalation LC50; 48245710: primary eye irritation; 48245711: primary dermal irritation; 48245712: dermal sensitization). In addition, there is a proposed label (with the signal word CAUTION), and a CSF dated March 1, 2007 (although this document indicates it is the CSF for EPA Reg. No. 81598-6).

## COMMENTS AND RECOMMENDATIONS:

1. The primary reviews of the acute toxicity studies were conducted by an EPA contractor (Summitec Corporation). The Technical Review Branch conducted the secondary reviews, and made revisions as appropriate.
2. All of the studies have been classified as acceptable, with the exception of the dermal sensitization study in MRID 48245712. Although there was no indication that the test material, Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C) is a dermal sensitizer, the positive control study was not conducted within 6 months as required by OPPTS 870.2600. The registrant should submit a positive control assay within the 6-month time period of the study on Nicosulfuron Technical, or, alternatively, can cite another study on this technical or use the cite-all method of support to satisfy this data requirement. The registrant could also accept labeling indicating that this test material is a dermal sensitizer.
3. The following is the acute toxicity profile for the formulation that was tested, based on the results of the acute toxicity studies:

Acute oral toxicity	III	Acceptable	MRID 48245707
Acute dermal toxicity	III	Acceptable	MRID 48245708
Acute inhalation toxicity	IV	Acceptable	MRID 48245709
Primary eye irritation	III	Acceptable	MRID 48245710
Primary dermal irritation	IV	Acceptable	MRID 48245711
Dermal sensitization	Negative	Unacceptable <sup>a</sup>	MRID 48245712

<sup>a</sup> Although there was no indication that the test material is a dermal sensitizer, the positive control study was not conducted within 6 months of the study on the test material, as required by OPPTS 870.2600.

4. Based on the acute toxicity profile above, and taking into consideration the proposed uses specified on the label and information in the CSF, the following is the tentative (pending a resolution of the dermal sensitization study requirement) precautionary and first aid labeling for EPA File Symbol 87122-R [NAB NICO TECH] as obtained from the Label Review System:

**PRODUCT ID #:** 087122-00001

**PRODUCT NAME:** NAB NICO TECH

#### **PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

#### **Hazards to Humans and Domestic Animals:**

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]

[Protective eyewear may be specified, if appropriate].

#### **First Aid:**

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

5. The registrant has proposed a toxicity category III inhalation first aid statement. This is acceptable.
6. The CSF (dated March 1, 2007) for 87122-R should also be reviewed and accepted by the TRB Chemistry Team. It is noted that the copy provided to this reviewer indicates that it is the CSF for EPA Reg. No. 81598-6.

**STUDY TYPE:** Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 423

**TEST MATERIAL:** Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)

**CITATION:** Sílvia Delano do Amaral Guimarães (2009) Acute Oral Toxicity Study in Wistar Hannover Rats for Nicosulfuron Technical. Final Report RF-6640.305.620.08. Bioagri Laboratórios, Fazenda Lagoa Bonita, Chácara 13, Caixa Postal: 08287-Planaltina/DF – 73310-970 – Brazil. 25 p. August 14, 2009. MRID 48245707.

**SPONSOR:** Zibo Nab Agrochemicals Limited, North of National High- Tech Industrial Development Zone, Zibo City, Shandong Province, 256410, China

**EXECUTIVE SUMMARY:** In an acute oral toxicity study (MRID 48245707), two groups of three fasted (overnight), adult female Wistar Hannover rats (age: 11 weeks; body weight: 200-220 g; source: Bioagri Laboratórios, DF/Brazil) were given a single dose of Nicosulfuron Technical (960.0-986.8 g/kg Nicosulfuron; Batch No. 080419) as a dilution (200 mg/mL) in corn oil at a dose of 2000 mg/kg bw by gavage and observed for 14 days.

All animals survived, had no specific clinical signs, and gained weight (both from day 0 to 7 and again from day 7 to 14) throughout the study. No gross lesions were found at necropsy.

LD<sub>50</sub> Females > 2000 mg/kg bw

**Based on the observed LD<sub>50</sub> in females, Nicosulfuron Technical is classified as EPA Toxicity Category III for oral toxicity.**

This study is classified as acceptable. It does satisfy the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 423) in the rat.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## RESULTS AND DISCUSSION:

Individual animals were dosed as follows:

TABLE 1. Doses, mortality/animals treated			
Dose (mg/kg)	Males	Females	Combined
2000	-	0/3	-
2000	-	0/3	-

**Statistics:** No statistical analysis was required since all animals survived. The oral LD<sub>50</sub> was observed as being > 2000 mg/kg.

- A. **Mortality:** All animals survived the study.
- B. **Clinical observations:** No specific clinical signs were found during the study. All animals gained weight (both from day 0 to 7 and again from day 7 to 14) throughout the study.
- C. **Gross necropsy:** No specific macroscopic findings were found at necropsy.
- D. **Reviewer's conclusions:** This reviewer agrees with the study author's conclusions. Based on the observed LD<sub>50</sub> in females, Nicosulfuron Technical is classified as EPA Toxicity Category III.
- E. **Deficiencies:** None

**STUDY TYPE:** Acute Dermal Toxicity – Rat; OPPTS 870.1200; OECD 402

**TEST MATERIAL:** Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)

**CITATION:** Marcelo Fontana da Silveira (2009) Acute Dermal Toxicity Study in Wistar Hannover Rats for Nicosulfuron Technical. Final Report RF-6640.310.597.08. Bioagri Laboratórios, Fazenda Lagoa Bonita, Chácara 13, Caixa Postal: 08287-Planaltina/DF – 73310-970 – Brazil. 23 p. July 30, 2009. MRID 48245708.

**SPONSOR:** Zibo Nab Agrochemicals Limited, North of National High- Tech Industrial Development Zone, Zibo City, Shandong Province, 256410, China

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 48245708), adult Wistar Hannover rats (5/sex; age: 8-11 weeks; body weight: males: 252-292 g and females: 204-231 g; source: Bioagri Laboratórios, DF/Brazil) were dermally exposed for 24 hours on an area of approximately 10% of the total body surface area on the clipped dorsal trunk to 2000 mg/kg bw Nicosulfuron Technical (960.0-986.8 g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C) as received. The test material was applied to a gauze dressing, moistened with deionized water, and placed on the dose area. The gauze dressing and entire trunk were wrapped with semi-occlusive dressing. The animals were observed for 14 days.

All animals survived and had no specific clinical findings during the study. One female lost 10 g during the second week; however, all animals gained weight during the study. No gross lesions were noted at necropsy.

LD<sub>50</sub> Males > 2000 mg/kg bw

LD<sub>50</sub> Females > 2000 mg/kg bw

LD<sub>50</sub> Combined > 2000 mg/kg bw

**Based on the observed LD<sub>50</sub>, Nicosulfuron Technical is classified as EPA Toxicity Category III for dermal toxicity.**

This study is classified as acceptable. It does satisfy the guideline requirements for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## RESULTS AND DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
2000	0/5	0/5	0/10

**Statistics:** No statistical analysis was required since all animals survived at the limit dose. The dermal LD<sub>50</sub> was observed as being > 2000 mg/kg.

- A. **Mortality:** All animals survived the study.
- B. **Clinical observations:** All animals had no specific clinical findings. One female lost 10 g during the second week; however, all animals gained weight during the study.
- C. **Gross necropsy:** No gross lesions were noted.
- D. **Reviewer's conclusions:** This reviewer agrees with the study author's conclusions. Based on the LD<sub>50</sub>, Nicosulfuron Technical is classified as EPA Toxicity Category III for dermal toxicity.
- E. **Deficiencies:** None



Reviewer: Byron T. Backus, Ph.D.  
Risk Manager (EPA): 25

Date: June 16, 2011

**STUDY TYPE:** Acute Inhalation Toxicity – Rat; OPPTS 870.1300; OECD 403

**TEST MATERIAL:** Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)

**CITATION:** Tainá Rangel Pinagé (2009) Nicosulfuron Technical – Acute Inhalation Toxicity Test of Nicosulfuron Technical in Rats (*Rattus norvegicus*). Final Report RF-6640.309.541.08. Bioagri Laboratórios, Fazenda Lagoa Bonita, Chácara 13, Caixa Postal: 08287-Planaltina/DF – 73310-970 – Brazil. 29 p. August 11, 2009. MRID 48245709.

**SPONSOR:** Zibo Nab Agrochemicals Limited, North of National High- Tech Industrial Development Zone, Zibo City, Shandong Province, 256410, China

**EXECUTIVE SUMMARY:** In an acute inhalation toxicity study (MRID 48245709), young adult Wistar Hannover rats (5/sex/group; age: 9 (males) -11 (females) weeks; body weight: males: 269-300 g and females: 194-232 g; source: Bioagri's (DF) rearing house) were exposed by nose-only inhalation to Nicosulfuron Technical (960.0-986.8 g/kg Nicosulfuron; Batch No. 080419) for 4 hours at a concentration of 5.243 mg/L. The animals were then observed for 14 days. The MMADs of two equally time-spaced air samples were 4.779 and 4.330  $\mu\text{m}$  and the GSD 2.143 and 2.055.

All animals survived the study. All animals exhibited kyphosis (reported as an acute respiratory sign; the usual definition is curvature of the back, which was here presumably related to difficulties in breathing) starting and reverting within the first day of exposure. No test material related gross lesions were noted in any animal at necropsy.

LC<sub>50</sub> Males > 5.243 mg/L  
LC<sub>50</sub> Females > 5.243 mg/L  
LC<sub>50</sub> Combined > 5.243 mg/L

**Based on the observed LC<sub>50</sub>, Nicosulfuron Technical is classified as EPA Toxicity Category IV for inhalation toxicity.**

This study is classified as acceptable. It does satisfy the guideline requirements for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## RESULTS AND DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD $\mu\text{m}$	GSD	Mortality/Number Tested		
				Males	Females	Combined
Not reported	5.243	4.799, 4.330	2.143, 2.055	0/5	0/5	0/10

**Statistics:** No statistical analysis was required since all animals survived at the limit dose. The dermal  $\text{LC}_{50}$  was observed as being  $> 5.243 \text{ mg/L}$ .

**Test Atmosphere / Chamber Description:** The grinded and sieved test material was aerosolized (details not reported). The chamber used was a Jaegar Inhalation Chamber, Mark II with a Wright Dust Feeder integrated system. Rats were exposed to the aerosolized test material in plexiglass nose-only tubes.

Gravimetric Conc. (mg/L):	5.243
Chamber Volume (L):	Not reported
Total Airflow (L/min):	10
Temperature (room)	20.3-21.8°C
Relative Humidity (room)	60-62%
Time to equilibrium:	Not reported

**Test atmosphere concentration:** During exposure, air samples were collected eight times with filters using an air sampling pump from the breathing zone of the animals. Filters were weighed before and after sampling. The mean actual concentration of the test material on the aerosol was calculated as follows: the ratio between the samples' mean weight and the sampling flow rate multiplied by sampling time.

**Particle size determination:** Particle size for each exposure concentration was determined twice using an seven-stage In-Tox cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined (details not reported).

**A. Mortality:** All animals survived the study.

**B. Clinical observations:** All animals exhibited kyphosis (reported as an acute respiratory sign; the usual definition is curvature of the back, which was here presumably related to difficulties in breathing) starting and reverting within the first day of exposure. All animals gained weight over the 14-day post-exposure period.

- C. **Gross necropsy:** No test material related gross lesions were noted in any animal at necropsy.
- D. **Reviewer's conclusions:** This reviewer agrees with the study author's conclusions. Based on the LC<sub>50</sub>, Nicosulfuron Technical is classified as EPA Toxicity Category IV by the inhalation exposure route.
- E. **Deficiencies:** Temperature and relative humidity in the exposure tubes, equilibrium time in the exposure chamber, chamber volume, details procedures of aerosolization of the test material, and nominal concentration of the test material in the chamber were not reported. These deficiencies would not affect the result of the study.

Reviewer: Byron T. Backus, Ph.D.  
Risk Manager (EPA): 25

Date: June 16, 2011

**STUDY TYPE:** Primary Eye Irritation – Rabbit; OPPTS 870.2400; OECD 405

**TEST MATERIAL:** Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)

**CITATION:** Barbara Canabrava Frossard de Faria (2009) Acute Eye Irritation/Corrosion Study in Rabbits with Nicosulfuron Technical. Final Report RF-6640.312.762.08. Bioagri Laboratórios, Fazenda Lagoa Bonita, Chácara 13, Caixa Postal: 08287-Planaltina/DF – 73310-970 – Brazil. July 29, 2009. 22 p. MRID 48245710.

**SPONSOR:** Zibo Nab Agrochemicals Limited, North of National High- Tech Industrial Development Zone, Zibo City, Shandong Province, 256410, China

**EXECUTIVE SUMMARY:** In a primary eye irritation study (MRID 48245710), 0.1 g of sieved Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; pH 5.78 at 1% concentration and 23.1°C) was instilled as received into the conjunctival sac of the left eye of two male and one female young adult New Zealand White rabbits (age: 17 weeks; source: Granja Angolana's rabbitry, São Roque/São Paulo, Brazil). The untreated eye served as a control. The animals were observed for 72 hours post-instillation.

Corneal opacity was not noted for any rabbit during the study. Iritis was noted in 2/3 rabbits one hour after test material instillation with clearance by 24 hours. Positive conjunctival irritation was noted for all rabbits one hour after test material instillation with clearance for two rabbits by 24 hours and for one rabbit by 48 hours.

**Nicosulfuron Technical was minimally irritating based on the highest maximum mean total score of 6.0, recorded one hour after test material instillation, and based on eye irritation persisting for more than 24 hours but clearing within 7 days or less, the test material is classified as EPA Toxicity Category III for primary eye irritation.**

This study is classified as acceptable. It does satisfy the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## RESULTS AND DISCUSSION:

	Number "positive"/Number treated			
	Hours			
Observations	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	2/3	0/3	0/3	0/3
Conjunctivae:				
Redness*	3/3	1/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge**	0/3	0/3	0/3	0/3

\* Score of 2 or more required to be considered "positive"

\*\* Discharge is not a positive effect according to the grading scale

- A. **Observations:** Corneal opacity was not noted for any rabbit during the study. Iritis was noted in 2/3 rabbits one hour after test material instillation with clearance by 24 hours. Positive conjunctival irritation was noted for all rabbits one hour after test material instillation with clearance for two rabbits by 24 hours and for one rabbit by 48 hours.
- B. **Results:** Nicosulfuron Technical was minimally irritating. The highest maximum mean total score was 6.0, recorded one hour after test material instillation (calculated by the reviewer).
- C. **Reviewer's conclusions:** The study author concludes that the test material produced conjunctival hyperemia, edema, and secretion in all rabbits with clearance by 48 hours. This reviewer agrees with the study author's conclusions and classifies Nicosulfuron Technical as minimally irritating and as EPA Toxicity Category III for primary eye irritation.
- D. **Deficiencies:** None.

**STUDY TYPE:** Primary Dermal Irritation – Rabbit; OPPTS 870.2500; OECD 404

**TEST MATERIAL:** Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)

**CITATION:** Barbara Canabrava Frossard de Faria (2009) Acute Dermal Irritation/Corrosion Study in Rabbits with Nicosulfuron Technical. Final Report RF-6640.311.604.08. Bioagri Laboratórios, Fazenda Lagoa Bonita, Chácara 13, Caixa Postal: 08287-Planaltina/DF – 73310-970 – Brazil. July 27, 2009. 21 p. MRID 48245711.

**SPONSOR:** Zibo Nab Agrochemicals Limited, North of National High- Tech Industrial Development Zone, Zibo City, Shandong Province, 256410, China

**EXECUTIVE SUMMARY:** In a primary dermal irritation study (MRID 48245711), two male and one female young adult New Zealand White rabbits (age: 16-19 weeks; source: Granja Angolana's rabbitry, São Roque/São Paulo, Brazil) were dermally exposed to 0.5 g of Nicosulfuron Technical (960.0-986.8 g/kg Nicosulfuron; Batch No. 080419; pH 5.78 at 1% concentration and 23.1°C) for 4 hours. The test material was placed on a moistened gauze dressing and applied on an approximately 6 cm<sup>2</sup> area of the clipped back skin. The dressing was held by an adhesive and non-irritating Micropore tape. The coverings were removed after exposure. The animals were observed and irritation was scored at 1, 24, 48, and 72 hours after patch removal.

No irritation was noted on any rabbit during the study.

**In this study, Nicosulfuron Technical was not irritating (primary dermal irritation index = 0.0) and is classified as EPA Toxicity Category IV for primary dermal irritation.**

This study is classified as acceptable. It does satisfy the guideline requirements for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## RESULTS AND DISCUSSION:

Animal Number	Sex	Hours			
		1	24	48	72
58	M	0/0 <sup>a</sup>	0/0	0/0	0/0
59	F	0/0	0/0	0/0	0/0
60	M	0/0	0/0	0/0	0/0
Severity of Irritation – Mean Score		0.0	0.0	0.0	0.0

<sup>a</sup> Erythema/edema

- A. **Observations:** No irritation was noted on any rabbit during the study.
- B. **Results:** Nicosulfuron Technical was not irritating. The Primary Dermal Irritation Index (PDII) is 0.0.
- C. **Reviewer's conclusions:** The study author concluded that the test material did not cause any dermal irritation. This reviewer agrees with the study author's conclusions. Based on the lack of irritation noted in the study, Nicosulfuron Technical is classified as EPA Toxicity Category IV for primary dermal irritation.
- D. **Deficiencies:** None

**STUDY TYPE:** Dermal Sensitization – guinea pig; OPPTS 870.2600; OECD 406

**TEST MATERIAL:** Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)

**CITATION:** Marândola, R. (2009) Skin Sensitization Test for Nicosulfuron Technical in Guinea pigs (*Cavia porcellus*). Final Report RF-6640.318.564.08. Bioagri Laboratórios, Fazenda Lagoa Bonita, Chácara 13, Caixa Postal: 08287-Planaltina/DF – 73310-970 – Brazil. August 3, 2009. MRID 48245712.

**SPONSOR:** Zibo Nab Agrochemicals Limited, North of National High- Tech Industrial Development Zone, Zibo City, Shandong Province, 256410, China

**EXECUTIVE SUMMARY:** In a dermal sensitization study (MRID 48245712) with Nicosulfuron Technical (960.0-986.8 g/kg Nicosulfuron; Batch No. 080419), 30 female young adult Hartley guinea pigs (age: 12-13 weeks; body weight: 433-627 g; source: Anilab Ltda, SP, Brazil) were tested using the Buehler Method. The test animals (20 females) were induced with 0.5 g of diluted test material in deionized water for approximately six hours. The procedure was repeated once each week for three consecutive weeks. Fourteen days after the third induction, the test animals were challenged with 0.5 g of test material in deionized water under occlusion to naive sites. The naive control animals (10 females) were treated with 1 mL of deionized water during inductions and 0.5 g of test material in deionized water under occlusion at challenge. Reactions were scored 30 and 54 hours after test material applications. The reliability check study with hexylcinnamaldehyde diluted in DMSO as the positive control substance was performed in July 2008 which is beyond six months of the current study.

After three consecutive weekly inductions, dermal reactions were not noted on any animals after challenge.

**Based on the results of this study, Nicosulfuron Technical was not a dermal sensitizer.**

This study is classified as unacceptable. It does not satisfy the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pigs. The experimental phase of the study was from March 9, 2009 to April 8, 2009. The positive control study was performed in July 2008, and was not conducted within six months of the current study.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## **PROCEDURE:**

- A. Induction:** The animals were induced and challenged according to the Buehler method. Two animals were used for the pilot study to determine the highest non-irritating



concentration of the test material prior to the induction and challenge dose. The flank areas of 20 test guinea pigs were clipped prior to each treatment. For induction, 0.5 g of test material (= 1 mL test solution at 50% w/v in deionized water) loaded to cotton lint patches was placed on the left flank of the animals and secured with occlusive dressing. The dressing was removed after approximately six hours and excess test material removed. The procedure was repeated once each week for three consecutive weeks. Reactions were scored 30 and 54 hours after the induction applications.

- B. Challenge:** Fourteen days after the third induction, the test animals were challenged with 0.5 g of diluted test material in deionized water under occlusion to naive sites for approximately 6 hours. Reactions were scored at 30 and 54 hours after challenge application.
- C. Naive control:** The flank areas of 10 naive control animals were clipped prior to treatment. The control animals were induced with 1 mL of deionized water three times as for the test animals. At challenge, the naive control group was treated with 0.5 g of diluted test material in deionized water for approximately 6 hours. Reactions were scored at 30 and 54 hours following challenge application.

## **RESULTS AND DISCUSSION:**

- A. Reactions and durations:** No dermal reaction was noted on any animal during the inductions or challenge. The test material was not a dermal sensitizer.
- B. Positive control:** The report included the results of a positive control (alpha-hexylcinnamaldehyde) study conducted beyond six months of the current study; although the results were appropriate.
- C. Reviewer's conclusion:** This reviewer agrees with the study author that the test material was not a dermal sensitizer. A positive control study performed within six months of the current study and with appropriate results is needed to validate the study and classify the study acceptable.
- D. Deficiencies:** A positive control study performed within six months of the current study was not included in the study.

**ACUTE TOX ONE-LINERS:**

<b>1. DP BARCODE:</b> DP384655				
<b>2. PC CODE:</b> 129008				
<b>3. CURRENT DATE:</b> May 9, 2011				
<b>4. TEST MATERIAL:</b> Nicosulfuron Technical (960.0 [declared], 986.8 [analyzed] g/kg Nicosulfuron; Batch No. 080419; solid, pH 5.78 at 1% concentration and 23.1°C)				
<b>Study/Species/Lab Study # / Date</b>	<b>MRID</b>	<b>Results</b>	<b>Tox. Cat.</b>	<b>Core Grade</b>
Acute oral toxicity/rat Bioagri Laboratórios RF-6640.305.620.08 / August 14, 2009	48245707	LD <sub>50</sub> Females > 2000 mg/kg bw.	III	A
Acute dermal toxicity/rat Bioagri Laboratórios RF-6640.310.597.08 / July 30, 2009	48245708	LD <sub>50</sub> Males > 2000 mg/kg bw LD <sub>50</sub> Females > 2000 mg/kg bw LD <sub>50</sub> Combined > 2000 mg/kg bw	III	A
Acute inhalation toxicity/rat Bioagri Laboratórios RF-6640.309.541.08 / August 11, 2009	48245709	LC <sub>50</sub> Males > 5.243 mg/L LC <sub>50</sub> Females > 5.243 mg/L LC <sub>50</sub> Combined > 5.243 mg/L	IV	A
Primary eye irritation/rabbit Bioagri Laboratórios RF-6640.312.762.08 / July 29, 2009	48245710	Minimally irritating; Corneal opacity was not noted for any rabbit during the study. Iritis was noted in 2/3 rabbits one hour after test material instillation with clearance by 24 hours. Positive conjunctival irritation was noted in all rabbits one hour after test material instillation with clearance on two rabbits by 24 hours and on one rabbit by 48 hours. The highest maximum mean total score was 6.0, recorded one hour after test material instillation.	III	A
Primary dermal irritation/rabbit Bioagri Laboratórios RF-6640.311.604.08 / August 14, 2009	48245711	Not irritating; No irritation was noted on any rabbit during the study. The Primary Irritation Index (PII) is 0.0.	IV	A
Dermal sensitization/Guinea pig Bioagri Laboratórios RF-6640.318.564.08 / August 14, 2009	48245712	Not sensitizing	-	U

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

## DATA EVALUATION RECORD

NAB NICO TECH  
[Nicosulfuron (98%)]

**STUDY TYPE:** Product Identity and Composition (OPPTS 830.1550)  
Description of Materials Used to Produce the Product (OPPTS 830.1600)  
Description of the Formulation Process (OPPTS 830.1650)  
Discussion of Formation of Impurities (OPPTS 830.1670)  
Preliminary Analysis (OPPTS 830.1700)  
Certified Limits (OPPTS 830.1750)  
Enforcement Analytical Method (OPPTS 830.1800)  
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRID 482457-01 through 482457-06

Prepared for  
Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Prepared by  
Summitec Corporation  
9724 Kingston Pike, Suite 602  
Knoxville, Tennessee 37922

Task Order No. 3-A-31

Primary Reviewer:  
Dennis M. Opresko, Ph.D.

Signature: 

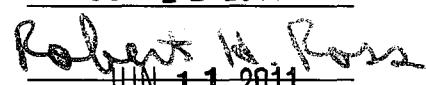
Date: JUN 11 2011

Secondary Reviewers:  
Eric Lewis, M.S.

Signature: 

Date: JUN 11 2011

Robert Ross, M.S., Program Manager

Signature: 

Date: JUN 11 2011

Quality Assurance:  
Angie Edmonds, B.S.

Signature: 

Date: JUN 11 2011

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

**BARCODE:** 384654; **Reg. No. /FILE SYMBOL No.:** 87122-R; **PRODUCT:** NAB NICO TECH  
Decision #440456

**DATE:** 06/17/11

**SUBJECT:** Product Chemistry Review of NAB NICO TECH

**FROM:** Indira Gairola (TRB EPA)  
Product Chemistry Team  
Technical Review Branch/RD (7505P)

*sgw 6/20/11*

**TO:** Kable Davis PM Team 25  
Herbicide Branch / RD (7505P)"

DP BARCODE: 384654  
DECISION No.: 440456  
REGISTRATION NO./FILE SYMBOL NO.: 87122-R  
PRODUCT NAME: NAB NICO TECH  
PC CODE: 129008  
REGISTRANT: ZIBO NAB AGROCHEMICALS  
USE: Herbicide  
FOOD USE: Yes [X] No [ ]  
MRID Numbers: 482457-01 through 48245706

**INTRODUCTION:** The current submission is for the technical grade active ingredient, Nicosulfuron (98%), to be used in the manufacture of herbicides. The submission includes Group A and Group B data requirements, amended basic CSF (dated 06/01/11) and proposed label. The Primary review was done by Summitec Corporation, 9724 Kingston Pike, Suite 602 Knoxville, Tennessee Task Order No. 3-A-11

#### SUMMARY OF FINDINGS:

##### 1. 830 series group Group A guidelines:

830.1550 (product identity & composition): TGA1 and impurities identified and composition determined based on the analysis of 5 batches of the product (MRID 482457-01).

830.1600 (description of materials used to produce the product): Starting materials described and MSDSs provided for each (MRID 482457-01).

830.1620 (description of production process): NAB NICO TECH is produced by a [REDACTED]  
Descriptions and process diagrams are provided for each step (MRID 482457-01).

830.1670 (discussion on the formation of impurities): Impurities are present in NAB NICO TECH as a result of unreacted starting material, intermediate reaction products, and unintended side reactions (MRID 482457-01). The registrant states that there are no impurities in NAB NICO TECH that could be considered to be of toxicological concern.

830.1700 (preliminary analysis): The average concentration of the TGA1 for 5 batches was 99.1% with a maximum value of 99.5% and a minimum of 98.6% (MRID 482457-02).

830.1750 (certified limits): Certified limits of TGA1, as shown on the CSF, are within the standard certified limits. Upper certified limits of impurities in concordance with the results of the preliminary analysis. The amended basic CSF dated 06/01/11 is acceptable.

\*Manufacturing process information may be entitled to confidential treatment\*

830.1800 (enforcement analytical method): The validity of a liquid chromatographic method for the analysis of NAB NICO TECH was supported by tests for linearity, selectivity, recovery, repeatability and intermediate precision (482457-03).

2. 830 series Group B guidelines (physical-chemical properties):

Product chemistry data submitted for guidelines 830.6302 (color); 830.6303 (physical state); 830.6304 (odor); 830.6313 (stability); 830.7000 (pH); 830.7050 (UV/visible absorption); 830.7200 (melting point); 830.7300 (density); 830.7370 (dissociation constants in water); 830.7550 (partition coefficient); 830.7840 (water solubility); 830.7950 (vapor pressure) are acceptable.

Product chemistry data for guidelines 830.6319 (Miscibility); 830.6321 (Dielectric breakdown voltage); 830.7220 (Boiling point); 830.7520 (Particle size, fiber length, and diameter distribution) are not applicable.

The registrant requests waivers for the product chemistry data requirements for 830.6314 (oxidation/reduction:chemical incompatibility); 830.6315 (flammability) and 830.6316 (explosibility).

The registrant states that product chemistry data requirements for 830.6317 (storage stability) and 830.6320 (corrosion characteristics) are not required unless requested by the Agency.

**CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for NAB NICO TECH TGA1 (produced by ZIBO NAB AGROCHEMICALS, LTD) and has concluded that:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed CSF for the basic formulation is acceptable. The nominal concentration of the TGA1 listed on the label is in agreement with that on the CS. The amended basic CSF dated 06/01/11 is acceptable.
3. The product chemistry data submitted corresponding to 830 series group B (physical-chemical properties) are acceptable except that the registrant must submit data for guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics). One year storage stability and corrosion characteristics tests must be conducted in the commercial containers. It is recommended that the observations be made at 0, 3, 9, and 12 months.
4. **NOTE:** The proposed label has a typographical error; the chemical name of the a.i. is spelled incorrectly. A corrected label may be submitted.

**BARCODE:** 384654; **Reg. No. /FILE SYMBOL No.:** 87122-R; **PRODUCT:** NAB NICO TECH  
Decision #440456

830.1550. Product identity & composition: (MRID No. 482457-01)

Common Name: Nicosulfuron

Chemical name (CAS): 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethyl-3-pyridinecarboxamide

(IUPAC): 2-(4,6-dimethoxypyrimidin-2-ylcarbamoysulfamoyl)-N,N-dimethylnicotinamide

CAS No.: 111991-09-4

PC Code No.: 129008

Empirical Formula: C<sub>15</sub>H<sub>18</sub>N<sub>6</sub>O<sub>6</sub>S

Molecular Weight: 410.4

Structural Formula:

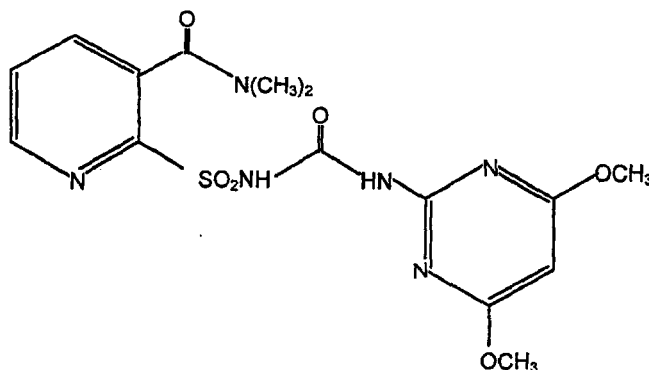


Table 1. Manufacturing and Impurity Data for NAB NICO TECH				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	482457-01	A	TGAI and impurities described and quantified
830.1600	Description of materials used to produce the product	482457-01	A	Starting materials described and MSDSs provided.
830.1620	Description of production process	482457-01	A	Descriptions and process diagrams are provided.
830.1670	Discussion of formation of impurities	482457-01	A	Impurities adequately described; none considered to be toxicologically significant.
830.1700	Preliminary analysis	482457-02	A	Five batches analyzed
830.1750	Certified limits	CSF	A	Within standard certified limits
830.1800	Enforcement analytical method	482457-03	A	Liquid chromatographic method validated.

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ;  
U = Up-grade (additional information required);

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of NAB NICO TECH				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	482457-04	A	White
830.6303	Physical state	482457-04	A	Powder
830.6304	Odor	482457-04	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	482457-04	A	Test results at 20±1 °C and 54°C and in the presence of iron, aluminum, aluminum acetate and ferric acetate
830.6314	Oxidation/reduction: chemical incompatibility	482457-06	W	Waiver requested. Does not contain any material that would be considered an oxidizing or reducing agent.
830.6315	Flammability	482457-06	W	Waiver requested. Material is a solid and not expected to be flammable.
830.6316	Explodability	482457-06	W	Waiver requested. Material does not have chemical bonds or functional groups associated with explosive chemicals.
830.6317	Storage stability	482457-06	G	Registrant states that storage stability data are not required unless specifically requested by the Agency
830.6319	Miscibility	482457-06	NA	Registrant states that the product is not an emulsifiable liquid to be diluted with petroleum solvents
830.6320	Corrosion characteristics	482457-06	G	Registrant states that corrosion characteristics data are not required unless specifically requested by the Agency
830.6321	Dielectric breakdown voltage	482457-06	NA	Product is not an end-use product
830.7000	pH	482457-04	A	pH of 3.8 based on average of three tests
830.7050	UV/Visible absorption	482457-04	A	$\lambda_{max}$ = 238-240 nm
830.7100	Viscosity	482457-06	NA	Waiver requested; product is not a liquid
830.7200	Melting point	482457-04	A	169°C (average of three tests)
830.7220	Boiling point	482457-06	NA	Waiver requested; product is a solid
830.7300	Density	482457-04	A	0.43 g/cc <sup>3</sup>
830.7370	Dissociation constants in water (DC)	482457-04	A	pKa 4.6 @ 25 °C (literature citation)
830.7520	Particle size, fiber length, and diameter distribution	482457-06	NA	Waiver requested; product is not a fibrous material or water-insoluble
830.7550	Partition coefficient	482457-04	A	log Pow -1.8 log @ pH 7 (literature citation)
830.7840	Water solubility	482457-05 482457-04	A	0.0743 g/L (pH 4.17) 22000 ppm @ pH 7 (literature citation)
830.7950	Vapor pressure	482457-04	A	$1.2 \times 10^{-16}$ mm Hg (literature citation)
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers				

830.1800 (enforcement analytical method)

A liquid chromatographic method was used for the analysis of nicosulfuron in NICOSULFURON TECHNICAL. Results of the analysis are shown below:

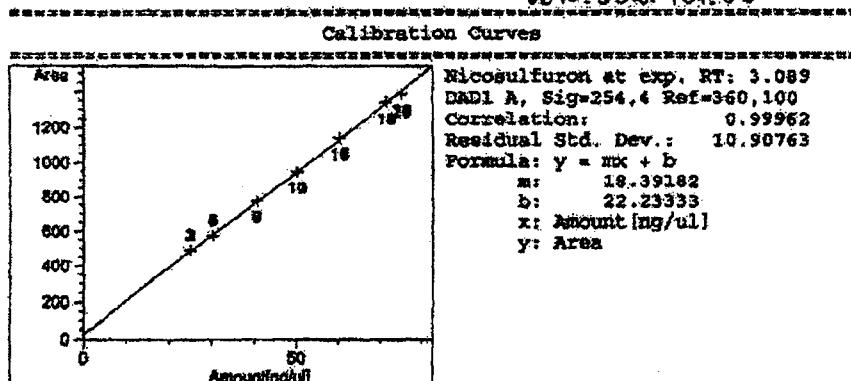
Table 9. Summary of the results.

Item	Result
Selectivity	There is no interference at the retention time of nicosulfuron
Linearity	Linear response over the tested range - nicosulfuron 25.060 ng $\mu\text{L}^{-1}$ to 75.180 ng $\mu\text{L}^{-1}$ correlation coefficient = 0.99962 gradient = 18.39182 (response / concentration) intercept = 22.23333 (response)  Limit of detection: 0.3522% Limit of quantification: 1.1741%
Precision	a) Repeatability NICOSULFURON TECHNICAL Average value = 98.75% (m/m) Standard deviation = 0.556% Uncertainty of the method = $\pm 0.398\%$ RSD = 0.563%  b) Intermediate precision  NICOSULFURON TECHNICAL Average value = 98.61% (m/m) Standard deviation = 0.484% Uncertainty of the method = $\pm 0.188\%$ RSD = 0.491%
Recovery	100.2 $\pm$ 1.30%

The calibration curve for the method is:

Method C:\HPCHEM\1\METHODS\100209.M

6640.032 431.08





**BARCODE:** 384654; **Reg. No. /FILE SYMBOL No.:** 87122-R; **PRODUCT:** NAB NICO TECH  
Decision #440456

Confidential appendix

830.1600 (description of materials used to produce the  
product):

**\*Pages 57-74 Manufacturing & Quality Control Process information may be entitled to confidential treatment\***

PYXIS REGULATORY CONSULTING, INC.

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
[www.PyxisRC.com](http://www.PyxisRC.com)

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June 1, 2011

OVERNIGHT DELIVERY

Katherine Montague (PM 25)/Linda Mascall  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Zibo NAB Agrochemicals Ltd.  
NAB Nico Tech (EPA File Symbol 87122-R)  
Submission of Amended CSF and Label

Dear Ms. Montague/Ms. Mascall,

On behalf of Zibo NAB Agrochemicals Ltd., we are submitting a revised Confidential Statement of Formula (CSF) for NAB Nico Tech based on a conversation with the EPA contractor at Summitec Corp. The chemical name in the Ingredients Statement was corrected on the NAB Nico Tech label. The CSF was revised as follows: Box 2 – EPA Est. No. added; Box 4 – EPA File Symbol added; Box 5 – EPA product manager revised; Box 10, for active ingredient – chemical name corrected; Box 21 – date revised.

Please forward these documents to the reviewer.

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Two (2) copies of the Confidential Statement of Formula (EPA Form 8570-4) for NAB Nico Tech dated June 1, 2011
3. Three (3) Copies of the revised label for NAB Nico Tech
4. Letter of Authorization

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



淄博新农基农药化工有限公司  
ZIBO NAB AGROCHEMICALS CO., LTD.

OCT 21 2009

21.10.2009

Document Processing Desk (COADR)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. (contact information below) is authorized to represent Zibo NAB Agrochemicals Ltd. (EPA Co. No. pending) before the US Environmental Protection Agency and California Department of Pesticide Regulation in all matters regarding our pesticide registrations and applications for registrations for nicosulfuron pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332  
T: (253) 853-7369  
F: (253) 853-5516

If you have any questions, please do not hesitate to contact me.

Sincerely,

*Changlu Shao*

(Frank Shao)  
President  
Zibo NAB Agrochemicals Ltd.

cc: Pyxis Regulatory Consulting, Inc.

地址: 山东省淄博市开发区北首博丰南路  
电话: 0086-533-8409995 8407222

邮编: 256410  
传真: 0086-533-8409985



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 87122-R	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zibo NAB Agrochemicals Ltd./NAB Nico Tech	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Zibo NAB Agrochemicals Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised label and CSF per EPA reviewer.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Pyxis Regulatory Consulting, Inc.	Title Agent	Telephone No. (Include Area Code) (253)-853-7369
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Consultant	
4. Typed Name Ann M. Tillman	5. Date 6/11/2011	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 5, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PYXIS REGULATORY CONSULTING, INC.  
ZIBO NAB AGROCHEMICALS, LTD  
4110 136TH ST. NW  
GIG HARBOR, WA 98332-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 29-SEP-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-29-10

Experts In-Processing Signature: M F HARRINGTON Date 10-4-10 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>87122-R</u>		EPA Receipt Date: <u>9-29-10</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
		X				
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

- 11/10/12
- CSF Contains Technical & Impurities only.
  - Studies associated w/ jacket (MRID 482457) have passed 86-5 review
  - Jacket passes

MRID 482457

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web



site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 1, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-440456  
EPA File Symbol or Registration Number: 87122-R  
Product Name: NAB NICO TECH  
EPA Receipt Date: 29-Sep-2010  
EPA Company Number: 87122  
Company Name: ZIBO NAB AGROCHEMICALS, LTD

JANELLE KAY  
PYXIS REGULATORY CONSULTING, INC.  
ZIBO NAB AGROCHEMICALS, LTD  
4110 136TH ST. NW  
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R330

NEW MANUFACTURING USE PRODUCT;OLD AI;SELECTIVE CITATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Peresa Downs*  
Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{883099X~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?  
☐ volpay % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 25

Receipt No.

S-

883099

EPA File Symbol/Reg. No.

87122-R

Pin-Punch Date:

9/30/2010

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

R330

Granted:

R330

Amount Due: \$ 17,136

## Parent/Child Decisions:

S883100 / 87122-E



Technical & impurities only  
Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: JDL

Date: 10/1/10

Remarks:

- basically cife - all except for a few selectively  
afed studies (labeled "OLD")

Sarah Greubel

---

From: paygovadmin@mail.doc.twai.gov  
Sent: Monday, September 27, 2010 3:04 PM  
To: Sarah Greubel  
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 251IR2C0  
Agency Tracking ID: 74141501930

Name On Account: Pyxis Regulatory Consulting, Inc.  
Transaction Type: ACH Debit  
Transaction Amount: \$17,136.00  
Payment Date: Sep 28, 2010  
Account Type: Business Checking  
Routing Number: 125107671  
Account Number: \*\*\*\*\*0080

Transaction Date: Sep 27, 2010 6:03:58 PM Number of Payments Scheduled: 1  
Frequency: OneTime  
Decision Number:

Registration Number: Nicosulfuron - Technical Company Name: Zibo NAB Agro Company Number:  
87122 Action Code: R330



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Zibo NAB Agrochemicals Ltd 4110 136th St. NW Gig Harbor, WA 98332, 253- 853-7369	EPA Registration Number/File Symbol 87122
Active Ingredient(s) and/or representative test compound(s) Nicosulfuron	Date 9/27/10
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food, Terrestrial non-food	Product Name NAB Nico Tech

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.


Signature <i>Ann M. Tillman</i>	Date 9/27/10	Typed or Printed Name and Title Ann M. Tillman, Agent
------------------------------------	-----------------	--

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

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## DATA MATRIX

Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 1 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550	Product Identity and Composition	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
830.1620	Description of Production Process	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
830.1650	Description of Formulation Process				Not Required <sup>1</sup>
830.1670	Discussion of Formation of Impurities	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
830.1700	Preliminary Analysis	Volume 2	Zibo NAB Agrochemicals Ltd.	OWN	
830.1750	Certified Limits	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
830.1800	Enforcement Analytical Method	Volume 3	Zibo NAB Agrochemicals Ltd.	OWN	
830.6302	Color	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.6303	Physical State	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.6304	Odor	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	Data
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010



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## DATA MATRIX


Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 2 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Data Waiver <sup>2</sup>
830.6315	Flammability	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Waiver <sup>3</sup>
830.6316	Explosibility	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Waiver <sup>4</sup>
830.6317	Storage Stability	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	PR-92-5 <sup>5</sup>
830.6319	Miscibility	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Not Applicable <sup>6</sup>
830.6320	Corrosion Characteristics	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	PR-92-5 <sup>5</sup>
830.6321	Dielectric Breakdown Voltage	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Not Required <sup>6</sup>
830.7000	pH	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.7050	UV/Visible Absorption	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.7100	Viscosity	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Not Applicable <sup>6</sup>
830.7200	Melting Point/Melting Range	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.7220	Boiling Point/Boiling Range	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Not Required <sup>7</sup>
830.7300	Density/Relative Density/Bulk Density	Volume 4	Zibo NAB Agrochemicals Ltd.	OWN	
830.7370	Dissociation Constants in Water	Volume 4	Zibo NAB Agrochemicals Ltd.	PL	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

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## DATA MATRIX


Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 3 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle Size, Fiber Length, and Diameter Distribution	Volume 6	Zibo NAB Agrochemicals Ltd.	OWN	Not Applicable <sup>6</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 4	Zibo NAB Agrochemicals Ltd.	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 5	Zibo NAB Agrochemicals Ltd.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 4	Zibo NAB Agrochemicals Ltd.	PL	
<b>Generic Data Requirements</b>					
850.2100 (71-1)	Acute Avian Oral Toxicity	Cite-All		PAY	
850.2200 (71-2)	Avian Dietary Toxicity	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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## DATA MATRIX

Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 4 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2300 (71-4)	Avian Reproduction	Cite-All		PAY	
850.2400 (71-3)	Wild Mammal Toxicity				Not required <sup>8</sup>
850.1075 (72-1)	Freshwater Fish Toxicity	40924216 40924217 41360109 41360110		OLD OLD OLD OLD	See endnote <sup>9</sup>
850.1010 (72-2)	Freshwater Invertebrate Toxicity	Cite-All		PAY	
850.1075 (72-3(a))	Estuarine/Marine Toxicity: Fish	Cite-All		PAY	
850.1025, 850.1035, 850.1045, 850.1055 (72-3(b,c))	Estuarine/Marine Toxicity: Mollusk and Shrimp	Cite-All		PAY	
850.1300 (72-4)	Aquatic Invertebrate Life Cycle	Cite-All		PAY	
850.1500 (72-5)	Fish Life Cycle	Cite-All		PAY	
850.1710, 850.1730, 850.1850 (165-4)	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

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## DATA MATRIX


Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 5 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.3020 (141-1)	Honeybee Acute Contact Toxicity	Cite-All		PAY	
850.4100 (122-1(a))	Tier 1: Seed Germination/Seedling Emergence	Cite-All		PAY	
850.4150 (122-1(b))	Tier 1: Vegetative Vigor	Cite-All		PAY	
850.4400 (122-2)	Tier 1: Aquatic Plant Growth	Cite-All		PAY	
850.4100 (123-1(a))	Tier 1: Seed Germination/Seedling Emergence	Cite-All		PAY	
850.4150 (123-1(b))	Tier 2: Vegetative Vigor	Cite-All		PAY	
850.4400 (123-2)	Tier 2: Aquatic Plant Growth	Cite-All		PAY	
870.1100	Acute Oral Toxicity: Rat	Volume 7	Zibo NAB Agrochemicals Ltd.	OWN	
870.1200	Acute Dermal Toxicity: Rat	Volume 8	Zibo NAB Agrochemicals Ltd.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	Volume 9	Zibo NAB Agrochemicals Ltd.	OWN	
870.2400	Primary Eye Irritation: Rabbit	Volume 10	Zibo NAB Agrochemicals Ltd.	OWN	
870.2500	Primary Dermal Irritation	Volume 11	Zibo NAB Agrochemicals Ltd.	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

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## DATA MATRIX

Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 6 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Dermal Sensitization	Volume 12	Zibo NAB Agrochemicals Ltd.	OWN	
870.6100 (81-8)	Acute Neurotoxicity – Rat	Cite-All		PAY	
870.3100 (82-1)	90-Day Oral - Rodent	Cite-All		PAY	
870.3150 (82-1)	90-Day Oral – Non-rodent	Cite-All		PAY	
870.3200 (82-2)	21/28-Day Dermal	Cite-All		PAY	
870.4100 (83-1)	Chronic Feeding: Rat	Cite-All		PAY	
83-1(b)	Chronic Feeding: Non-Rodent				Not required
870.4200 (83-2)	Carcinogenicity	Cite-All		PAY	
870.3700 (83-3)	Prenatal Developmental Toxicity – Rat and Rabbit	Cite-All		PAY	
870.3800 (83-4)	Reproduction and Fertility Effects	Cite-All		PAY	
870.5100 (84-2(a))	Bacterial Reverse Mutation Assay	Cite-All		PAY	
870.5300, 870.5375 (84-2(b))	<i>In vitro</i> Mammalian Cell Assay	Cite-All		PAY	
870.5385, 870.5395 (84-4)	<i>In vivo</i> Cytogenetics	Cite-All		PAY	
870.6200 (82-5(a))	90-Day Neurotoxicity – Rat	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010


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## DATA MATRIX

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Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7485 (85-1)	Metabolism and Pharmacokinetics	Cite-All		PAY	
870.7800	Immunotoxicity	Cite-All		PAY	
875.1100	Dermal Outdoor Exposure	Cite-All		PAY	
875.1200	Dermal Indoor Exposure				Not required <sup>10</sup>
875.1300	Inhalation Outdoor Exposure	Cite-All		PAY	
875.1400	Inhalation Indoor Exposure				Not required <sup>11</sup>
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues	Cite-All		PAY	
875.2200	Soil Residue Dissipation	Cite-All		PAY	
875.2300	Indoor Surface Residue Dissipation				Not required <sup>12</sup>
875.2400	Dermal Exposure	Cite-All		PAY	
875.2500	Inhalation Exposure	Cite-All		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

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**DATA MATRIX**

Date April 22, 2010			EPA Reg. No./File Symbol 87122-	Page 8 of 12	
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product  NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120 (161-1)	Hydrolysis	40924220		OLD	See endnote <sup>13</sup>
835.2240 (161-2)	Photodegradation in Water	Cite-All		PAY	
835.2410 (161-3)	Photodegradation on Soil	Cite-All		PAY	
835.4100 (162-1)	Aerobic Soil Metabolism	Cite-All		PAY	
835.4200 (162-2)	Anaerobic Soil Metabolism	Cite-All		PAY	
835.4400 (162-3)	Anaerobic Aquatic Metabolism	Cite-All		PAY	
835.4300 (162-4)	Aerobic Aquatic Metabolism	Cite-All		PAY	
835.1230, 835.1240 (163-1)	Leaching and Adsorption/Desorption	Cite-All		PAY	
835.6100 (164-1)	Terrestrial Field Dissipation Study	Cite-All		PAY	
835.6200 (164-2)	Aquatic (Sediment) Field Dissipation Study				Not required
835.6300 (164-3)	Forestry Field Dissipation Study				Not required
See 850.1710, 860.1400, 860.1850 for 165-4, 165-3 and 165-1 citations, respectively.					
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010


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## DATA MATRIX

Date April 22, 2010			EPA Reg. No./File Symbol 87122-		Page 9 of 12
Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1100 (171-2)	Chemical Identity	Volume 1	Zibo NAB Agrochemicals Ltd.	OWN	
860.1200 (171-3)	Directions for Use	See label			
860.1300 (171-4(a))	Nature of the Residue in Plants	41082626		OLD	See endnote <sup>14</sup>
860.1300 (171-4(b))	Nature of the Residue in Livestock	Cite-All		PAY	
860.1340 (171-4(c),(d))	Residue Analytical Methods	41082632 41472101 43023102		OLD OLD OLD	See endnote <sup>15</sup>
860.1380 (171-4(e))	Storage Stability	41082626 43344401		OLD OLD	See endnote <sup>16</sup>
860.1480 (171-4(j))	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs				Not required <sup>17</sup>
860.1500 (171-4(k))	Magnitude of the Residue in Plants - Corn	41082629 43344402		OLD OLD	See endnote <sup>18</sup>
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010




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## DATA MATRIX

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Applicant's/Registrant's Name & Address Zibo NAB Agrochemicals Ltd. North of National High-Tech Industrial Development Zone Zibo City, 256410 P. R. China			Product NAB Nico Tech		
Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520 (171-4(I))	Magnitude of Residue in Processed Food/Feed - Corn	41082630 43344403		OLD OLD	See endnote <sup>19</sup>
860.1850 (165-1)	Confined Crop Rotation Study	Cite-All		PAY	
860.1900	Field Accumulation in Rotational Crops	Cite-All		PAY	
201-1	Droplet Size Spectrum	Cite-All		PAY	
202-1	Droplet Size Spectrum	Cite-All		PAY	
<b>Nicosulfuron Product Specific and Generic Data Requirements</b>					
Zibo NAB Agrochemicals Ltd. will make offers-to-pay to the following companies on the data submitters list of March 31, 2010.					
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		E. I. DuPont de Nemours and Co. Inc.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Cheminova A/S	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

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## DATA MATRIX

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Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		BASF Corporation	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Agan Chem. Mfg. Ltd.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Albaugh Inc.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Makhteshim-Agan of North America Inc.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Spray Drift Task Force	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Cheminova Inc.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		ISK Biosciences Corp.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Outdoor Residential Exposure Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010


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Ingredient Nicosulfuron (CAS No. 111991-09-4)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Agricultural Reentry Task Force	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		FIFRA Endangered Species Task Force, LLC	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Agricultural Handlers Exposure Task Force	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Gro-Pro LLC	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Rotam Ltd.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Etigra LLC	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Rotam Agrochemical Co. Ltd.	PAY	
	Cite-All under Selective Method utilized by Zibo NAB Agrochemicals Ltd.		Sharda USA LLC	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Apr. 22, 2010

## Endnotes for Data Matrix for NAB Nico Tech

- 
- <sup>1</sup> **830.1650** - These data are not required for the registration of a manufacturing use product. See 830.1620 for production process information.
- <sup>2</sup> **830.6314** - Zibo NAB Agrochemicals Ltd. requests a waiver from the requirement for determination of the chemical incompatibility (oxidation/reduction). Nicosulfuron does not contain any material that would be considered to be an oxidizing or reducing agent (please refer to the Confidential Statement of Formula for NAB Nico Tech). The MSDS for this product indicates that the following materials can be use as appropriate fire extinguishing agents: foam, dry chemical, carbon dioxide, or water spray. Under DOT regulations, nicosulfuron is not considered hazardous when shipped. HMIS and NFPA ratings indicate this material is not highly reactive (rating of 0) nor flammable (rating of 1). Sufficient emergency response information is available for handling nicosulfuron technical. Therefore, Zibo NAB Agrochemicals Ltd. respectfully requests a waiver from the requirement of these data for NAB Nico Tech.
- <sup>3</sup> **830.6315** - Zibo NAB Agrochemicals Ltd. requests a waiver from the requirement of this data requirement since NAB Nico Tech is a solid and is not expected to be flammable. Please refer to the Confidential Statement of Formula for NAB Nico Tech.
- <sup>4</sup> **830.6316** - Zibo NAB Agrochemicals Ltd. requests a waiver from this data requirement because nicosulfuron does not have the chemical bonds or functional groups associated with explosive chemicals. Please refer to the Confidential Statement of Formula for NAB Nico Tech.
- <sup>5</sup> **830.6317, 830.6320** - Per PR Notice 92-5, these data are not required to be submitted unless specifically requested by the Agency. Zibo NAB Agrochemicals Ltd. agrees to conduct these studies if required and requests that the study be made a condition of registration.
- <sup>6</sup> **830.6319, 830.6321, 830.7100, 830.7520** - NAB Nico Tech is a solid and not an emulsifiable concentrate and is not to be diluted with petroleum solvents. Therefore, miscibility data are not applicable to this technical. NAB Nico Tech is not to be used around electrical equipment and data for dielectric breakdown constant are not required for technical materials. NAB Nico Tech is a solid and not a liquid, therefore, viscosity data are not applicable to this product. Zibo NAB Agrochemicals Ltd. is seeking a waiver for this data requirement for NAB Nico Tech because the product is not a fibrous material nor a water-insoluble material.
- <sup>7</sup> **830.7220** - NAB Nico Tech is a solid and boiling point data are not required for solids. Data for melting point are required for solids. See Guideline 830.7200.
- <sup>8</sup> **850.2400 (71-3)** - These data are not required for the registration of nicosulfuron (please refer to the 870 series). No data have been submitted to support this registration.
- <sup>9</sup> **850.1017 (72-1)** - According to March 2, 1990 EPA memo, the studies cited are considered acceptable and satisfy the data requirement.
- <sup>10</sup> **875.1200** - Product not proposed for application indoors.
- <sup>11</sup> **875.1400** - Product not proposed for application indoors.
- <sup>12</sup> **875.2300** - Product not proposed for application indoors.
- <sup>13</sup> **835.2120 (161-1)** - According to a Feb. 22, 1990 EPA memo, the study cited is considered acceptable and satisfies the data requirement.
- <sup>14</sup> **860.1300 (171-4(a))** - According to an April 23, 1990 EPA memo and HED TRED risk assessment, the study cited is considered acceptable and satisfies the data requirement.
- <sup>15</sup> **860.1340 (171-4(c,d))** - According to an April 23, 1990 EPA memo, the studies cited, plus responsive submissions, satisfy the data requirement.
- <sup>16</sup> **860.1380 (171-4(e))** - According to an April 23, 1990 EPA memo, the study cited and subsequent additional submissions appear to be acceptable and satisfies the data requirement.

## Endnotes for Data Matrix for NAB Nico Tech

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- <sup>17</sup> **860.1480 (171-4(j))** – According to an April 23, 1990 EPA memo and HED TRED risk assessments, these data are not required because residue data did not demonstrate detectable residues.
- <sup>18</sup> **860.1500 (171-4(k))** – According to an April 23, 1990 EPA memo and HED TRED risk assessments, the studies cited appear to be acceptable and satisfy the data requirement.
- <sup>19</sup> **860.1520 (171-4(l))** – According to an April 23, 1990 EPA memo and HED TRED risk assessments, the studies cited appear to be acceptable and satisfy the data requirement.

# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
087122-xxxxx	Sept. 27, 2010	087122-xxxxx.20100402.NAB Nico Tech label v1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature  
Ann M. Tillman  
Consultant, Zibo NAB Agrochemicals Ltd.

Sept. 27, 2010  
Date



淄博新农基农药化工有限公司  
ZIBO NAB AGROCHEMICALS CO.,LTD.

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U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. (contact information below) is authorized to represent Zibo NAB Agrochemicals Ltd. (EPA Co. No. pending) before the US Environmental Protection Agency and California Department of Pesticide Regulation in all matters regarding our pesticide registrations and applications for registrations for nicosulfuron pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332  
T: (253) 853-7369  
F: (253) 853-5516

If you have any questions, please do not hesitate to contact me.

Sincerely,

*Changlu Shao*

(Frank Shao)  
President  
Zibo NAB Agrochemicals Ltd.

cc: Pyxis Regulatory Consulting, Inc.

地址: 山东省淄博市开发区北首博丰南路  
电话: 0086-533-8409995 8407222

邮编: 256410  
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4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

September 27, 2010

OVERNIGHT DELIVERY

Jim Tompkins (PM 25)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Zibo NAB Agrochemicals Ltd.  
NAB Nico Tech (EPA File Symbol 87122- )  
Application for New Pesticide Registration

Dear Mr. Tompkins,

On behalf of Zibo NAB Agrochemicals Ltd., we are submitting an application for registration of NAB Nico Tech, a technical containing the active ingredient nicosulfuron. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Copy of the PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies of each report):

<b>48245701</b>	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities and Certified Limits for NAB Nico Technical. <b><i>Contains Confidential Business Information.</i></b>
<b>48245702</b>	Volume 2	830.1700	Sardinha, R. G. Qualitative and Quantitative Profile of the Test Substance Nicosulfuron Technical (Five Batch Analysis). <b><i>Contains Confidential Business Information</i></b>
<b>48245703</b>	Volume 3	830.1800	Cobra, J. Analytical Method Validation for the Active Ingredient Nicosulfuron in Technical Product.



<b>48245704</b>	Volume 4	830.6302, 830.6303, 830.6304, 830.6313, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550-7570, 830.7950	Sun, G. Nicosulfuron Technical Grade Active Ingredient Physical and Chemical Characteristics.
<b>48245705</b>	Volume 5	830.830.7840-7860	Cobra, J. Solubility in Water and Organic Solvents of Nicosulfuron Technical.
<b>48245706</b>	Volume 6	830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7520	Tillman, A. M. Nicosulfuron Technical Waiver Request for Physical and Chemical Properties.
<b>48245707</b>	Volume 7	870.1100	Amaral Guimaraes, S. D. Acute Oral Toxicity Study in Wistar Hannover Rats for Nicosulfuron Technical.
<b>48245708</b>	Volume 8	870.1200	Silveira, M. F. Acute Dermal Toxicity Study in Wistar Hannover Rats for Nicosulfuron Technical.
<b>48245709</b>	Volume 9	870.1300	Pinage, T. R. Acute Inhalation Toxicity Test of Nicosulfuron Technical in Rats ( <i>Rattus norvegicus</i> ).
<b>48245710</b>	Volume 10	870.2400	Frossard de Faria, B. C. Acute Eye Irritation/Corrosion Study in Rabbits with Nicosulfuron Technical.
<b>48245711</b>	Volume 11	870.2500	Frossard de Faria, B. C. Acute Dermal Irritation/Corrosion Study in Rabbits with Nicosulfuron Technical.
<b>48245712</b>	Volume 12	870.2600	Marandola, R. W. Skin Sensitization Test for Nicosulfuron Technical in Guinea Pigs ( <i>Cavia porcellus</i> ) (Buehler Test Method).

We would like to note that Zibo NAB Agrochemicals Ltd. is using the selective method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Zibo NAB Agrochemicals Ltd. submitted notices of intent to apply and offers to pay to all companies on the March 31, 2010 Data Submitter's List. This action falls under PRIA category R330 (48: New manufacturing use product; registered active ingredient; selective data citation). This technical product is substantially similar to a currently registered product. The fee for this action is \$17,136 and has been paid. The decision timeline is 12 months. Please note that this submission is tied to another concurrent submission: application for registration for the end use product NICON 75 WDG.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 87122 - R	2. EPA Product Manager J. Tompkins	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zibo NAB Agrochemicals Ltd./NAB Nico Tech	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Zibo NAB Agrochemicals Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 81598-6 Product Name Rotam Nicosulfuron Technical	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R330 (48: New manufacturing use product; registered active ingredient; selective data citation) because it is an application for registration (using the selective method of support) for a new technical product substantially similar to a currently registered product. The fee which has been paid is \$17,135 and the decision timeline is 12 months.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	lined fiber drum
* Certification must be submitted				<input checked="" type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Pyxis Regulatory Consulting, Inc.		Title Agent	
		Telephone No. (Include Area Code) (253)-853-7369	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant	
4. Typed Name Ann M. Tillman		5. Date 9/27/10	

